



MAR 18 2005

Mr. Gus Fenton
Director of Quality Assurance
and Product Development
CNS, Inc.
7615 Smetana Lane
Eden Prairie, Minnesota 55344

Dear Mr. Fenton:

This is in response to your letter of February 23, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statements will be made for the products FiberChoice® Chewable tablets and FiberChoice® drops:

“Inulin helps keep blood sugar levels more uniform.”
“Inulin found in FiberChoice helps keep blood sugar levels more uniform”
“FiberChoice helps keep blood sugar levels more uniform”
“Soluble fiber found in FiberChoice helps keep blood sugar levels more uniform.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to a claim about the control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar level that is already within normal limits implies that the product is intended to treat elevated blood sugar levels (diabetes), which is a disease. Therefore, because the claims you are making for these products represent that the products are intended to affect blood sugar levels but do not also include a statement about them being intended to affect blood sugar levels that are already in the normal ranges, they are implied disease claims.

Page 2 - Mr. Gus Fenton

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-CE840



The
Breathe Right
Company

February 23, 2005

MAR - 2

Food & Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740

Subject: Notification of Structure/Function Claims, Dietary Supplement
CNS, Inc., Minneapolis, MN 55439
FiberChoice® chewable tablets and FiberChoice® drops

This letter shall serve as a notification for the use of structure/function claims in the labeling and advertising of a dietary supplement in accordance with 21 CFR 101.93. CNS, Inc. uses the structure/function claims on the following page with the dietary supplements FiberChoice® chewable tablets and FiberChoice® drops. The dietary ingredient of interest is fiber in the form of inulin. Both products contain four grams of inulin in a dose.

These claims will be accompanied by the following disclaimer upon the next printing of labels and labeling material.

"These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease."

This information is complete and accurate. CNS has substantiation that these statements are truthful and not misleading. If you have any questions, please feel free to contact me at the numbers provided below.

Sincerely,

Gus Fenton
Director of Quality Assurance and Product Development
Phone (Direct): 952.229.1595 Fax: 952.229.1700

E-mail: gfenton@cns.com

CNS, Inc. 7615 Smetana Lane

Eden Prairie, Minnesota 55344

phone (952) 229 1500 fax (952) 229 1700

www.cns.com

91016

CNS, Inc.
Minneapolis, MN 55439
FiberChoice® chewable tablets and FiberChoice® drops

Structure/Function Claims to be made on product label and labeling material

"Inulin helps boost calcium absorption*."

"Inulin found in FiberChoice helps boost calcium absorption*."

"Soluble fiber found in FiberChoice helps boost calcium absorption*."

"FiberChoice helps boost calcium absorption*."

"Inulin helps your body absorb calcium*."

"Inulin found in FiberChoice helps your body absorb calcium*."

"Soluble fiber found in FiberChoice helps your body absorb calcium*."

"FiberChoice helps your body absorb calcium*."

(Note: the claims above would be footnoted to the statement below)

"*Studies have shown that 8g per day of inulin (a natural dietary fiber) increases calcium absorption. Each serving of FiberChoice® contains 4g of inulin."

"Fiber is important to your overall health."

"Dietary fiber, like that found in FiberChoice, is important to your overall health."

"Soluble fiber found in FiberChoice is important to your overall health."

"Fiber can be an important part of your overall good health."

"Dietary fiber, like that found in FiberChoice, can be an important part of your overall good health."

"Soluble fiber found in FiberChoice can be an important part of your overall good health."

"FiberChoice can be an important part of your overall good health."

"FiberChoice promotes good digestive health and regularity."

"FiberChoice promotes good digestive health."

"FiberChoice promotes regularity."

"FiberChoice is a natural aid to good digestive health and regularity."

"FiberChoice is a natural aid to good digestive health."

"FiberChoice is a natural aid to regularity."

"FiberChoice helps maintain good digestive health and regularity."

"FiberChoice helps maintain good digestive health."

"FiberChoice helps maintain regularity."

"Fiber supports colon health."

"Dietary fiber found in FiberChoice supports colon health."

"Soluble fiber found in FiberChoice supports colon health."

"FiberChoice supports colon health."

"Inulin helps promote better digestion."

"Inulin found in FiberChoice helps promote better digestion."

"Soluble fiber found in FiberChoice helps promote better digestion."

"FiberChoice helps promote better digestion."

"Inulin promotes a healthy digestive system."

"Inulin found in FiberChoice promotes a healthy digestive system."

"Soluble fiber found in FiberChoice promotes a healthy digestive system."

"FiberChoice promotes a healthy digestive system."

"Inulin assists in restoring and maintaining intestinal flora."

"Inulin found in FiberChoice assists in restoring and maintaining intestinal flora."

"Soluble fiber found in FiberChoice assists in restoring and maintaining intestinal flora."

"FiberChoice assists in restoring and maintaining intestinal flora."

"Inulin is a prebiotic which helps grow beneficial bacteria for good digestive balance."

"Inulin found in FiberChoice is a prebiotic which helps grow beneficial bacteria for good digestive balance."

"FiberChoice contains a prebiotic (inulin) which helps grow beneficial bacteria for good digestive balance."

"Inulin provides prebiotic nutrients that help grow the beneficial bacteria and prevent harmful bacteria."

"Inulin found in FiberChoice provides prebiotic nutrients that help grow the beneficial bacteria and prevent harmful bacteria."

"FiberChoice provides prebiotic nutrients that help grow the beneficial bacteria and prevent harmful bacteria."

"Inulin helps keep blood sugar levels more uniform."

"Inulin found in FiberChoice helps keep blood sugar levels more uniform."

"FiberChoice helps keep blood sugar levels more uniform."

"Soluble fiber found in FiberChoice helps keep blood sugar levels more uniform."

"Soluble fiber like that found in FiberChoice helps control weight by helping you feel full longer."

"Inulin found in FiberChoice helps control weight by helping you feel full longer."

"FiberChoice helps control weight by helping you feel full longer."

"Soluble fiber found in FiberChoice helps control weight by helping you feel full longer."

Soluble fiber like that found in FiberChoice helps control weight by helping you feel full longer and curb cravings."

"Inulin found in FiberChoice helps control weight by helping you feel full longer and curb cravings."

"FiberChoice helps control weight by helping you feel full longer and curb cravings."

"Soluble fiber found in FiberChoice helps control weight by helping you feel full longer and curb cravings."

"Soluble fiber like that found in FiberChoice helps maintain weight by helping you feel full longer."

"Inulin found in FiberChoice helps maintain weight by helping you feel full longer."

"FiberChoice helps maintain weight by helping you feel full longer."

"Soluble fiber found in FiberChoice helps maintain weight by helping you feel full longer."

Soluble fiber like that found in FiberChoice helps maintain weight by helping you feel full longer and curb cravings."

"Inulin found in FiberChoice helps maintain weight by helping you feel full longer and curb cravings."

"FiberChoice helps maintain weight by helping you feel full longer and curb cravings."

"Soluble fiber found in FiberChoice helps maintain weight by helping you feel full longer and curb cravings."

"Inulin helps enhance your immune system."

"Inulin found in FiberChoice helps enhance your immune system."

"FiberChoice helps enhance your immune system."

"Soluble fiber found in FiberChoice helps enhance your immune system."

"Inulin helps enhance your immune system to keep you healthy."

"Inulin found in FiberChoice helps enhance your immune system to keep you healthy."

"FiberChoice helps enhance your immune system to keep you healthy."

"Soluble fiber found in FiberChoice helps enhance your immune system to keep you healthy."

"Inulin supports beneficial intestinal bacteria that helps keep you healthy by enhancing your immune system."

"Inulin found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by enhancing your immune system."

"Soluble fiber found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by enhancing your immune system."

"Inulin supports beneficial intestinal bacteria that helps keep you healthy by stimulating your immune system."

"Inulin found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by stimulating your immune system."

"Soluble fiber found in FiberChoice supports beneficial intestinal bacteria that helps keep you healthy by stimulating your immune system."

"Inulin helps strengthen your body's defense system."

"Inulin found in FiberChoice helps strengthen your body's defense system."

"FiberChoice helps strengthen your body's defense system."

"Soluble fiber found in FiberChoice helps strengthen your body's defense system."